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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,248	11/16/2001	Peter Krulevitch	IL-10896	5826
7590	12/07/2005		EXAMINER	
Eddie E. Scott Assistant Laboratory Counsel Lawrence Livermore National Laboratory P.O. Box 808, L-703 Livermore, CA 94551			JASTRZAB, JEFFREY R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/992,248	Applicant(s) KRULEVITCH ET AL.	
	Examiner Jeffrey R. Jastrzab	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-12,14,15,18-21,25-28 and 32-56 is/are pending in the application.
- 4a) Of the above claim(s) 32-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-12,14,15,18-21 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 32-56 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/13/05.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-12 are, and 19-21 and 25-28 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims call for the electrodes to positively transmit to the cells, to positively contact the cells, and to be connected to the eye, which amount to an inferential recitation of the body, thus making the claim non-statutory. The use of "adapted to" is suggested to overcome the issue.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6, 8-12, 19, 21 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite in that it claims elements of the combination (device) but only the electrode array is being claimed per the preamble.

Claims 6, 9, 12 and 21 lack sufficient structure to further limit the invention.

Claims 10, 19 and 26 are partly redundant in regards to the composition of the substrate.

Claim 25 is indefinite in that it calls for the implant to consist of a substrate, however additional structure exists (electrodes). For art interpretation, the flexible substrate will be read as closed-ended only and not the implant.

Claims 26-28 are indefinite in that the preambles refer to the combination (system) but only the electrode array is being claimed.

Claim Rejections - 35 USC § 103

Claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edell et al. in view of Pinchuk. Applicants' argue that the Edell et al. reference does not teach a conformable substrate composed entirely of a flexible and stretchable polymer. It appears that the "composed entirely of" limitation is intended to negate the possibility that other components or substrate layers exist, however, since the claim is drafted in open-ended format, the subject limitation can be interpreted to mean that the conformable substrate itself is flexible and stretchable,

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which the silicon encapsulation of Edell et al. is in fact. This layer would clearly provide a degree of support for the electrodes. Further, note that the electrodes are exposed through the substrate, thus making them embedded therein. As to the flexible and stretchable functions, silicone elastomer would inherently have these properties, however Edell et al. do not specifically call for polydimethylsiloxane as the substrate material. Pinchuk teaches (note column 2, lines 55+) that polydimethylsiloxane while not perfect for all applications is widely used in medical implants because it's an extremely stable elastomer. Given these disclosures, it would have been obvious to one of ordinary skill in the art to substitute use polydimethylsiloxane for the silicone elastomer in Edell et al's implant as a mere substitution of known functionally equivalent stretchable and flexible polymers, and further since Pinchuk et al. teach that the material is extremely stable which is a desirable characteristic for an implant. As to Claims 7-12 since Applicants' arguments are solely based on the amendments of the independent claim 1, the reasons of record apply equally here.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Jastrzab whose telephone number is (571) 272-4947. The examiner can normally be reached on M-W 5:30 a.m. to 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey R. Jastrzab
Primary Examiner
Art Unit 3762
12/2/05